



CUSTOMER NO. 000042131 docket no. 134.004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Rashida A. Karmali

Serial No. : 10/826,083 Group Art Unit : 1743
Filed : 04/16/2004 Examiner : Dwayne K. Handy.
For : Specimen Collection, processing and analytical Assembly

DECLARATION OF Rashida A. Karmali Under 37 C.F.R. 1.132

1. I am the inventor in the above referenced application. I am currently Chief Executive Officer and Chief Scientific Officer of SavviPharm Inc, located in New York, New York. I am beneficial owner of this invention. I have a Ph.D in Biochemistry (1976) and have published over 100 scientific articles.

2. The Final Action dated October 19, 2006 included the following Statements:

“Applicant’s arguments filed 7/21/06 have been fully considered but they are not persuasive. The previous rejection may be summarized as follows; Schramm teaches every element of the claims except for the materials, filter, colored reagents, and coated capillary. Nason provides a teaching of plastic materials, a filter and colored reagents. Liotta provides a coated capillary.

“Liotta also teaches the analysis of a sample by colorimetric or optical assay. Applicant has argued that Liotta does not, in fact, disclose the coated capillary. The Examiner disagrees. Liotta recites that a coated vaccutainer or coated capillary pipette could be utilized in collecting the sample (column 12, lines 46-67). (emphasis added)”

Response: I disagree with the examiner's conclusions for the following reasons.

Schramm

- a) As indicated above by the Examiner, Schramm does NOT teach 1) materials, 2) filter, 3) colored reagents and 4) coated capillary.
- b) In fact, Schramm's device does not have a filter and as such any sample collected will include undesirable debris since the sample is not filtered.
- c) Schramm's device does not contain the anticoagulant material in the capillary tube and therefore the blood sample would have to be processed rapidly or else it would coagulate.
- d) Schramm's device is not color coded and therefore samples would have to be labeled to identify the treatment in the capillary tube.

Nason

- e) Nason is cited for filters, plastic materials, and colored reagents. In col. 5, lines 58-62, Nason describes that the housing is made of plastic. However, plastic is NOT a distinguishing feature in the present invention.
- f) Similarly, in col. 9, lines 19-25, Nason describes that the vial 70 is placed in a colorimetric device to measure the color change. However, colorimetric measure of color change is not a distinguishing feature in this invention. The color change in the present invention is recorded more easily, i.e., visually and does not require a device.
- g) The filter members 18 and 19 are serially mounted and filter 19 terminates in a rounded contour, col. 8, lines 5-15. Col 9, lines 24-31, cited in the Action, describe optical detection in a device without requiring the vial to be touched. These features are NOT present in the present invention and in fact distinguish it from Nason.

Liotta

- h) Liotta does not provide a coated capillary- this is an inaccurate statement. the present invention in no way deals with interference caused by chelating metals. One skilled in the art would not find it advantageous to use Liotta's teachings on method of activating light emission by a photoprotein adapted for use in a diagnostic

assay and providing a substrate having a coated or impregnated with a dried salt of a metal cation and a dried caged metal cation compound to produce a dried metal cation zone.....Claim 1 of Liotta. The mere fact that Liotta mentions the word “capillary” does not make it relevant art.

i) By the Examiner’s own admission, Liotta recites a coated vaccutainer or coated capillary pipette. Both these devices are different and distinguishable from the capillary tube of the present invention. In fact, coated vaccutainers have been known in the art for a long time, and the vaccutainer tubes are especially pressurized to draw blood by suction. And pipettes that are coated have been used to draw samples by suction (mouth or rubber tip). However, there is no teaching in the art for capillary tubes being coated with anything and then used for drawing biological samples. This is because a very clean inside surface of the capillary tube is required to create a capillary force for the specimen to be drawn by this capillary force up the tube, and usually in very small volumes.

j) In fact, it was after several attempts that we standardized the coating of the capillary tube so the coating material(s) did not interfere with the drawing of the specimen or block the opening of the capillary tube.

k) One skilled in the art associates a capillary glass tube with the short thin glass tube which is open at both ends. This is used to collect blood, then one end is plugged by heating, and the tube is centrifuged to obtain the hematocrit.

3. Summary of Interview held with Examiner Dwayne Handy on October 16, 2006

I find it necessary to submit my account under Oath, of the Interview because it is at odds with the Examiner’s conclusion.

- a) Examiner Handy called at 10.45 am and summarily repeated the rejections made in the Office Action of March 23, 2006. He indicated that the response had addressed two references- Schramm and Nason but he was not convinced that the third reference – Liotta was overcome.
- b) I pointed out that Liotta was entirely a different invention category and that the Examiner was using hindsight in applying it. I also pointed out that the whole invention should be considered and that in fact there was a need for the invention because it allowed collection of small amounts of blood and prevented waste of blood as repeatedly shown in the specification.

c) Examiner Handy stated that he did not have time to work with me on this and would issue the next Final Action.

Therefore, based on the above arguments there is no basis to maintain the rejections of claims 1-15 and they should be withdrawn.

I hereby declare that all statements made hereto to my knowledge are true, and all statements made on information and beliefs are believed to be true; and further, that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon.

By:

Rashida A. Karmali

Rashida A. Karmali, Ph.D

Date: 12/18/2006